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09/988,494	11/20/2001	Tianmei Ouyang	LIFE040	8555

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EXAMINER:

DAVIS, RUTH A

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/17/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/988,494

Applicant(s)

OUYANG ET AL.

Examiner

Ruth A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 August 2003.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 and 33-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 33-42 is/are rejected.
- 7) ☒ Claim(s) 35-41 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Applicant's amendment and response filed August 4, 2003 has been received and entered into the case. Claims 11 – 32 are canceled; claims 33 – 42 are added. Claims 1 – 10 and 33 – 42 are pending and have been considered on the merits. All arguments have been fully considered.

#### *Claim Objections*

1. Claims 35 – 41 are objected to under 37 CFR 1.75 as being substantial duplicates of claims 5 - 11. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

#### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 33, 34 and their dependents are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not originally described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the claims include the new limitations “a

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molar ratio of about 0.02 to about 17” and “a molar ratio of about 50 to about 800”. The specification as originally filed does not describe such a molar ratio, nor does it specify if the ratios are molar or by weight. Therefore the limitations are rendered new matter.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 33, line 1 “the method” lacks sufficient antecedent basis.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1 – 2, 4 – 10 and 35 – 44 are rejected under 35 U.S.C. 102(a) as being anticipated by Ouyang.

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Applicant claims a reagent composition comprising a tetrazolium dye, phenazine electron transfer agent and a flavin agent effective to stabilize said composition. The flavin agent is FAD, the phenazine agent is PES, and the composition is dry or wet. The composition further contains an analyte oxidizing signal producing system, comprising an analyte oxidase or dehydrogenase; and an enzyme cofactor.

Ouyang teaches a reagent composition comprising a tetrazolium dye, FAD (coenzyme factor), oxidases and/or dehydrogenases and PES (p.4 – 5). The composition is wet or dry (p.5 0036).

The reference anticipates the claimed subject matter.

Applicant argues that Ouyang does not teach the specific amounts of flavin, does not teach the flavin as a stabilizer, and has less than the composition of the invention.

However, these arguments fail to persuade, because while the reference does not show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the specific amounts) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

8. Claims 1 – 2, 4 – 5, 8 – 9, 35, 36, 39 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Nippon Chemiphar Co.

Applicant claims a reagent composition comprising a tetrazolium dye, phenazine electron transfer agent and a flavin agent effective for stabilizing the composition. The flavin agent is FAD, and the composition is a fluid. The composition further contains an analyte oxidizing signal producing system, comprising an analyte oxidase; and an enzyme cofactor.

Nippon teaches a liquid reagent composition comprising tetrazolium salts, PMS (phenazine electron transfer agent), FAD, and analyte oxidases (abstract).

The reference anticipates the claimed subject matter.

Applicant argues that Nippon teaches the flavin as a cofactor, not a stabilizer and that the amounts required for the claimed invention are far higher than those for the reference composition.

However, these arguments fail to persuade, because while the reference does not show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the specific amounts) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

9. Claims 1 – 2, 4, 6, 8, 35, 37 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Steinbach.

Applicant claims a reagent composition comprising a tetrazolium dye, phenazine electron transfer agent and a flavin agent effective for stabilizing the composition. The flavin agent is

FAD; and the composition further contains an analyte oxidizing signal producing system, comprising an analyte dehydrogenase; and an enzyme cofactor.

Steinbach teaches reagent compositions comprising tetrazolium salts (col.4 line 44-59), PMS (phenazine electron transfer agent) (col.6 line 28-30), FAD (col.4 line 28-33), diaphorase (dehydrogenases) (col.6 line 28-30, col.3 line 22-28), and NAD (enzyme cofactor) (col.4 line 28-32).

The reference anticipates the claimed subject matter.

Applicant argues that Steinbach teaches the flavin as a cofactor, not a stabilizer and that the amounts required for the claimed invention are higher than those for the reference composition.

However, these arguments fail to persuade, because while the reference does not show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the specific amounts) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1 – 10 and 33 – 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nippon and Geisler.

Applicant claims a fluid or dry reagent composition comprising a tetrazolium dye, phenazine electron transfer agent and a flavin agent effective to stabilize the composition. The phenazine agent is PES, the flavin stabilizing agent is FAD and the Group IIIA compound is borate or boric acid. The composition further contains an analyte oxidizing signal producing system, comprising an analyte oxidase or dehydrogenase; and an enzyme cofactor. The flavin to dye are present at a ratio of 0.02 – 17. Applicant additionally claims a reagent comprising a tetrazolium dye, phenazine electron transfer agent and a Group IIIA compound in an amount effective to stabilize the composition, wherein the ratio of compound to dye is about 50 – 800. Finally, applicant claims a reagent comprising a tetrazolium dye, phenazine electron transfer agent, a Group IIIA compound and a flavin stabilizing agent.



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Nippon teaches a liquid reagent composition for diagnostic use, the composition comprising tetrazolium salts, PMS (phenazine electron transfer agent), FAD, and analyte oxidases (abstract).

Geisler teaches fluid and powder reagent compositions for diagnostic use, the compositions comprising tetrazolium salts, boric acid, dehydrogenases and NAD (enzyme cofactor) (col.1-4).

The references do not teach the compositions with the claimed ratios. However, at the time of the claimed invention it would have been well within the purview of one of ordinary skill in the art to optimize amounts of effective ingredients as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the reagents of Nippon and/or Geisler with a reasonable expectation for successfully obtaining an effective reagent composition.

The references do not teach the reagent compositions wherein both a Group IIIA compound and a flavin stabilizing agent are used. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the diagnostic reagents for their common use, as disclosed by the cited references above. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to combine the instant ingredients with a reasonable expectation for successfully obtaining an effective reagent composition. Although the references do not teach PES as the phenazine agent, it would have been well within the purview of one of ordinary skill in the art to use PES in the reagent composition obtained by the combined teachings, because it was a well known phenazine electron transferring agent (as evidenced by Ouyang et al.).

Applicant argues that the references do not teach the amounts or ratios of flavin and Group IIIA compound, or that they are effective for stabilizing the compositions.

However, these arguments fail to persuade for the reasons set forth above. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the reagents of Nippon and/or Geisler with a reasonable expectation for successfully obtaining an effective reagent composition.

13. Claims 1 – 2, 4 – 10, 33 and 35 – 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ouyang.

Applicant claims a reagent composition comprising a tetrazolium dye, phenazine electron transfer agent and a flavin agent effective to stabilize said composition. The flavin agent is FAD, the phenazine agent is PES, and the composition is dry or wet. The composition further contains an analyte oxidizing signal producing system, comprising an analyte oxidase or dehydrogenase; and an enzyme cofactor. The flavin and dye are present at a ratio of 0.02 – 17.

Ouyang teaches a reagent composition comprising a tetrazolium dye, FAD (coenzyme factor), oxidases and/or dehydrogenases and PES (p.4 – 5). The composition is wet or dry (p.5 0036).

Ouyang does not teach the compositions with the claimed ratios. However, at the time of the claimed invention it would have been well within the purview of one of ordinary skill in the art to optimize amounts of effective ingredients as a matter of routine experimentation.

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Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the reagents of Ouyang with a reasonable expectation for successfully obtaining an effective reagent composition.

14. Claims 1 – 2, 4 – 5, 8 – 9, 33, 35 – 36, 39 – 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nippon.

Applicant claims a reagent composition comprising a tetrazolium dye, phenazine electron transfer agent and a flavin agent effective for stabilizing the composition. The flavin agent is FAD, and the composition is a fluid. The composition further contains an analyte oxidizing signal producing system, comprising an analyte oxidase; and an enzyme cofactor. The flavin and dye are present at a ratio of 0.02 – 17.

Nippon teaches a liquid reagent composition comprising tetrazolium salts, PMS (phenazine electron transfer agent), FAD, and analyte oxidases (abstract).

Nippon does not teach the compositions with the claimed ratios. However, at the time of the claimed invention it would have been well within the purview of one of ordinary skill in the art to optimize amounts of effective ingredients as a matter of routine experimentation.

Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the reagents of Nippon with a reasonable expectation for successfully obtaining an effective reagent composition.

15. Claims 1, 2, 4, 6, 8, 33, 35, 37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steinbach.

Applicant claims a reagent composition comprising a tetrazolium dye, phenazine electron transfer agent and a flavin agent effective for stabilizing the composition. The flavin agent is FAD; and the composition further contains an analyte oxidizing signal producing system, comprising an analyte dehydrogenase; and an enzyme cofactor. The flavin and dye are present at a ratio of 0.02 – 17.

Steinbach teaches reagent compositions comprising tetrazolium salts (col.4 line 44-59), PMS (phenazine electron transfer agent) (col.6 line 28-30), FAD (col.4 line 28-33), diaphorase (dehydrogenases) (col.6 line 28-30, col.3 line 22-28), and NAD (enzyme cofactor) (col.4 line 28-32).

Steinbach does not teach the compositions with the claimed ratios. However, at the time of the claimed invention it would have been well within the purview of one of ordinary skill in the art to optimize amounts of effective ingredients as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the reagents of Steinbach with a reasonable expectation for successfully obtaining an effective reagent composition.

16. Claims 34, 35, 37 and 39 – 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geisler.

Applicant claims a reagent composition comprising a tetrazolium dye, phenazine electron transfer agent and a Group IIIA compound wherein the ratio of compound to dye is 50 - 800. The Group IIIA agent is borate or boric acid, and the composition is dry or wet. The

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composition further contains an analyte oxidizing signal producing system, comprising an analyte dehydrogenase; and an enzyme cofactor.

Geisler teaches fluid and powder reagent compositions comprising tetrazolium salts, boric acid, dehydrogenases and NAD (enzyme cofactor) (col.1-4).

Geisler does not teach the compositions with the claimed ratios. However, at the time of the claimed invention it would have been well within the purview of one of ordinary skill in the art to optimize amounts of effective ingredients as a matter of routine experimentation.

Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the reagents of Geisler with a reasonable expectation for successfully obtaining an effective reagent composition.

### ***Conclusion***

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); alt. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad  
October 16, 2003.



LEON B. LINKFORD, JR.  
PRIMARY EXAMINER